

## ***DRAFT***

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with \*\*\* on \*\*\*.

1. In the Claims:

Cancel Claims 1-2, 4-10 and 12-16 and replace them with the following claims:

--

17. A method for detecting non-spermine/non-spermidine N<sup>1</sup>-acetyltransferase (SSAT) activity in a mammal, wherein the SSAT substrate is amantadine and the acetylated form of the SSAT substrate is acetylamantadine comprising the steps of:

- a) incubating an amount of amantadine in a mammal;
- b) obtaining a tissue or cell or body fluid sample from the mammal; and
- c) detecting acetylamantadine in the sample; and
- d) correlating the presence of acetylamantadine to SSAT activity, wherein the presence of the acetylamantadine in the sample is indicative of SSAT activity in the mammal.

18. A method as in Claim 17, wherein the amount of amantadine is equivalent to 1-4 mg/kg.
19. A method as in Claim 17, wherein the sample is a blood or urine sample.
20. A method as in Claim 17, wherein the urine sample is collected 2-24 hours post- incubating said amantadine in the mammal.
21. A method as in Claim 17, wherein the urine sample is collected 8 hours post- incubating said amantadine in the mammal.
22. A method as in Claim 17, wherein the step of correlating the amount of acetylated non-spermine / non-spermidine SSAT substrate in the sample comprises correlating to a standard curve to determine the level of SSAT activity in the mammal.
23. A method as in Claim 17, wherein the acetylamantadine level is detected by gas chromatography.
24. A method for assaying non-spermine/non-spermidine SSAT activity in a mammal, wherein the SSAT substrate is amantadine and acetylated form of the SSAT substrate is acetylamantadine comprising the steps of:
  - a) contacting a test sample obtained from the mammal with amantadine;
  - b) measuring the amount of acetylamantadine produced; and

c) relating the amount of acetylamantadine produced to a level of SSAT activity by comparison to a standard curve.

25. The method of Claim 24, wherein the sample is a homogenate of a liver tissue and the contacting step is performed at a pH of about 7.8.

26. The method of Claim 26, wherein step a) comprises incubating the sample with the substrate for about 10 minutes at 37°C.

2. The following is Examiner's statement of reasons for allowance:

The specification is only enabled for amantadine as non-spermine/ non-spermidine substrate for SSAT, because the specification explicitly demonstrates that only acetylamantadine was detected with amantadine as a substrate for SSAT and that transgenic male mice over expressing SSAT had a level of SSAT activity in the liver that is 4 fold higher with amantadine as substrate than that observed in non-transgenic mouse (See Specification, Page 12, Lines 4-6). Furthermore, mouse liver preparations as SSAT source did not show spermidine acetylation (See Specification, Page 11, Line 17).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."